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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

AMARIN PHARMA, INC. and AMARIN PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. HIKMA PHARMACEUTICALS USA INC. et al., Defendants.	Case No.: 2:16-cv-02525-MMD-NJK (Consolidated with 2:16-cv-02562-MMD-NJK) **DEFENDANTS' OPPOSITION TO AMARIN'S MOTION FOR PARTIAL SUMMARY JUDGMENT**

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

GLOSSARY OF ABBREVIATIONS

’728 pat.	U.S. Patent No. 8,293,728
’715 pat.	U.S. Patent No. 8,318,715
’677 pat.	U.S. Patent No. 8,357,677
’652 pat.	U.S. Patent No. 8,367,652
’560 pat.	U.S. Patent No. 8,431,560
Amarin	Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited
Amarin Ex.	exhibit attached to the Declaration of Michael N. Kennedy (D.I. 234)
Apo B	apolipoprotein B
Br.	Amarin’s Motion for Partial Summary Judgment (D.I. 234)
Defendants	Defendants Hikma Pharmaceuticals USA Inc., Hikma Pharmaceuticals International Limited, Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd.
Defs. Ex.	exhibit attached to the Declaration of Claire A. Fundakowski
DHA	docosahexaenoic acid
EPA	eicosapentaenoic acid
FDA	U.S. Food and Drug Administration
Heinecke	Defendants’ invalidity expert, Jay Heinecke, M.D.
LDL-C	low-density lipoprotein cholesterol
POSA	Person of ordinary skill in the art
TG	Triglycerides
Toth	Amarin’s validity expert, Peter Toth, M.D.

I. INTRODUCTION

Amarin's motion for partial summary judgment should be denied. Defendants are not asserting invalidity based on anticipation, enablement, or indefiniteness, so Amarin's motion with respect to those defenses is moot. As to Defendants' written description defense under 35 U.S.C. § 112, there is at least a triable issue of fact as to whether the asserted claims are invalid, precluding summary judgment. Indeed, if Amarin's own litigation positions and expert testimony were accepted, the asserted claims would be invalid for lacking written description as a matter of law.

Amarin has asserted 15 claims directed to a method of treating a patient who has triglyceride levels of at least 500 mg/dL by administering 4 grams per day of purified eicosapentaenoic acid ("EPA"), an omega-3 fatty acid found naturally in fish oil. Fourteen of those 15 claims further require this method to have specific effects on a patient's blood levels—i.e., reducing triglycerides by certain percentages, avoiding any increase in low-density lipoprotein cholesterol ("LDL-C"), or reducing apolipoprotein B ("Apo B").

Defendants contend that all asserted claims are invalid as obvious (an issue the Court will need to reach only if the Court denies Defendants' pending summary judgment motion). As Amarin admits, "[a]s of March 2008, the date of invention for the patents at issue in this case, other TG-lowering medications existed," including Lovaza®, "an omega-3 fatty acid product[] [that] was FDA-approved for lowering TGs in patients with severe hypertriglyceridemia"—the same indication that Amarin later obtained for Vascepa®. Br. 2. While Lovaza was a mixture of EPA and another omega-3 fatty acid called DHA, there is no dispute that a purified EPA product called Epadel was approved in Japan to reduce triglycerides and in clinical use as of March 2008. *See* Defs. Ex. 1 (Toth Dep.) at 152:2-153:11. The exact dose of purified EPA claimed in Amarin's patents was also known. Dr. Toth admits that [redacted] *Id.* at 204:4-8. And as explained by Defendants' invalidity expert, Dr. Heinecke, the prior art further

showed that purified EPA achieved the same clinical effects on blood levels that the asserted claims require. Amarin Ex. 6 (Heinecke Opening Report) ¶¶ 238-44.

Amarin's patents thus claim nothing new, and each asserted claim is invalid because it "would have been obvious at the time the invention was made to a person having ordinary skill in the art" ("POSA"). 35 U.S.C. § 103. In fact, during prosecution of Amarin's patent applications, the Patent Office repeatedly found that the claims merely recite "a process made obvious by the prior art," and eventually allowed the patents to issue solely due to Amarin's mischaracterizations about the prior art and arguments that the claimed clinical effects were unpredictable. Amarin Ex. 6 (Heinecke Opening Report) ¶¶ 265, 271-73 (quoting '727 pat. March 2, 2012 Office Action).

Amarin, of course, disagrees that its claims are obvious, rehashing the same strained arguments it made during prosecution. In doing so, however, Amarin presents a theory of nonobviousness that, if accepted by the Court, would render the patents invalid for a different reason: lacking a sufficient written description. For example, Amarin's validity expert, Dr. Toth, opines that [redacted] Defs. Ex. 2 (Toth Reply Report) ¶ 162. In his view, it was not until [redacted] *Id.* ¶¶ 183, 233. That is, because prior art studies purportedly "did not report the lipid effects of purified EPA in persons with triglyceride levels of at least 500 mg/dL," Dr. Toth opines that they "did not teach or create an expectation that high purity EPA would avoid substantial LDL-C increases in persons with very high triglycerides." Defs. Ex. 3 (Toth Responsive Report) ¶ 90; *see also id.* ¶ 81 (same). In fact, according to Dr. Toth, *no method* of reducing triglycerides with 4 grams per day of EPA would have been obvious [redacted]

t[redacted] Defs. Ex. 1 (Toth Dep.) at 211:6-15. He further opines that the claimed effects on Apo B and reductions in triglycerides by certain percentages were "unexpected," and that there was a "lack of predictability" for those lipid parameters prior to the MARINE results. *See, e.g.*, Defs. Ex. 4 (Toth Opening Report) ¶ 222; Defs. Ex. 3 (Toth Responsive Report) ¶ 373; Defs. Ex. 2 (Toth Reply Report) ¶ 183.

But if the Court were to accept Amarin's positions and expert testimony about what a POSA would have believed based on the prior art, the asserted claims would be invalid for failure to comply with section 112 of the Patent Act, which mandates that a patent's "specification shall contain a written description of the invention." 35 U.S.C. § 112. This statutory "written description requirement" is not met unless the specification "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the [patent's] filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

Under this standard, accepting Amarin's expert testimony on obviousness would render the patents invalid as a matter of law. On their face, Amarin's patents—which were filed *before* the MARINE trial results—provide no relevant information above and beyond what was taught in the prior art. That is, the patents do not "show that [Amarin] actually invented" methods that reduce triglycerides with 4 grams per day of purified EPA, much less methods that reduce triglycerides by the claimed percentages, avoid increasing LDL-C, or reduce Apo B. As Dr. Toth admits, Amarin's patents disclose [redacted] at all. Defs. Ex. 1 (Toth Dep.) at 354:10-18. Thus, the patents lack what Dr. Toth insists would be needed merely to find the claims obvious. And as the Federal Circuit has made clear, "a description that does *not* render a claimed invention obvious does not sufficiently describe that invention for purposes of § 112." *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997).

The fact that Defendants assert their written description defense in the alternative, in the event the Court accepts Amarin's factual contentions rather than their own, does not diminish its force. The Federal Circuit recently invalidated claims for lacking written description under

similar circumstances in *Nuvo Pharmaceuticals (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368 (Fed. Cir. 2019). There, as here, "[t]he Generics defended against the [patentee's] infringement assertions by alleging that the asserted patents are invalid as obvious." *Id*. at 1374. After trial, the district court ruled for the patentee, "conclud[ing] that none of the asserted claims are obvious over the prior art because" a POSA "would not have reasonably expected [the claimed invention] to work." *Id*. at 1374-75. But the Federal Circuit nonetheless found the patent invalid because, based on the patentee's own insistence at trial that a POSA "would not have known or understood that [the claimed drug] is effective" for the claimed method, the Court held that "there is nothing in the specification of the patents-in-suit showing that the inventor *actually invented* the invention claimed," as required by section 112. *Id*. at 1380 (quotation omitted). The same logic applies here. As in *Nuvo*, if this Court were to "f[i]nd upon [Amarin]'s insistence as part of its obviousness analysis that ordinarily skilled artisans would not have expected [purified EPA] to be effective" for achieving the claimed effects, the asserted claims would be invalid as not described because "the specification provides no experimental data or analytical reasoning showing the inventor possessed" methods of achieving those effects. *Id*. at 1375, 1377.

Amarin's motion for partial summary judgment hinges on the premise that "expert testimony is *required* to support an invalidity defense," Br. 9, but that premise does not help Amarin because Defendants' written description defense is supported by Amarin's *own* expert testimony. In any event, the premise is wrong: "[A] patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification. After all, it is in the patent specification where the written description requirement must be met." *Univ. Of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004). Thus, the Federal Circuit has rejected the "argu[ment] that [a patent challenger] failed to present any expert testimony" on the issue of written description, holding that "there is no strict requirement for extrinsic evidence (expert or otherwise) … [to] determine whether the written description requirement has been satisfied." *Adang v. Umbeck*, 2007 WL 3120323, at *2 (Fed. Cir. Oct. 25,

2007). Defendants' alternative defense is further supported by their invalidity expert, Dr. Heinecke, who opined that under Amarin's theory of nonobviousness, "a POSA would not have believed that the inventors of the asserted patents had achieved th[ose] result[s] based on the specification either." Amarin Ex. 10 (Heinecke Reply Report) ¶¶ 183, 71, 204.

Amarin's own litigation positions and expert testimony, if accepted, establish Defendants' written description defense as a matter of law. At a minimum, they at least show a triable issue of fact, which is all that is required to defeat Amarin's motion.

II. CONCISE STATEMENT OF MATERIAL FACTS

Amarin's purported "undisputed facts" (Br. 5-8) are immaterial and do not warrant summary judgment of validity. The following facts establish at least a triable issue of fact as to whether the asserted claims are invalid for lack of written description.

1. Amarin's asserted patents claim priority to provisional applications filed on February 10, 2009 and April 29, 2009,[1] and Amarin argues that the asserted patents are entitled to a March 2008 priority date.[2]

2. Amarin's validity expert, Dr. Toth, states that his opinions "would not differ" if a POSA's understanding and expectations were assessed as of the actual filing dates of February 10, 2009 and April 29, 2009, instead of Amarin's alleged invention date of March 2008.[3]

3. Each of the 15 asserted claims require administering 4 grams per day of purified EPA to reduce triglycerides in patients with triglycerides of at least 500 mg/dL.[4]

4. Fourteen of the 15 asserted claims further require that administering 4 grams per day of purified EPA achieves one or more of the following clinical effects: (i) a reduction in

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[1] *See, e.g.*, Amarin Ex. 5 ('728 pat.).

[2] Defs. Ex. 4 (Toth Opening Report) ¶ 44 ("The opinions I have expressed in this report would not differ if the date of invention of the asserted claims is February 10, 2009 or April 29, 2009.").

[3] *Id.* ¶ 43.

[4] Amarin Ex. 5 ('728 pat.) Claims 1, 13, and 16; Defs. Ex. 5 ('715 pat.) Claim 14; Defs. Ex. 6 ('677 pat.) Claims 1, 7, and 8; Defs. Ex. 7 ('652 pat.) Claims 1, 7, and 8; Defs. Ex. 8 ('560 pat.) Claims 4, 7, and 17; Defs. Ex. 9 ('929 pat.) Claims 1 and 5.

triglycerides "of at least about" 20% or 25%[5]; (ii) no increase, no "substantial[]" increase, no "statistically significant" increase, or no "more than 5%" increase in LDL-C levels[6]; or (iii) a reduction in "apolipoprotein B.[7]"

5. Dr. Toth opines that as of March 2008, (i) it would not have been obvious to use 4 grams per day of EPA to reduce triglycerides in patients with triglycerides of at least 500 mg/dL[8]; (ii) there was a "lack of reasonable expectation that one would get a reduction of at least about [20% or] 25% in fasting triglycerides with purified EPA"[9]; (iii) "it would not have been predictable, and there would have been no reasonable expectation of success, that a patient could avoid a substantial increase in LDL-C" when administered 4 grams per day of purified EPA[10]; and (iv) a POSA "would have found VASCEPA's reduction in apo-B unexpected."[11]

6. Dr. Toth opines that in order to find it obvious to use 4 grams per day of purified EPA in patients with triglycerides of at least 500 mg/dL, a POSA would need to see [redacted] which would have to provide a [redacted] compared to other doses of EPA.[12]

[5] Amarin Ex. 5 ('728 pat.) Claim 13; Defs. Ex. 6 ('677 pat.) Claim 7; Defs. Ex. 7 ('652 pat.) Claim 7; Defs. Ex. 8 ('560 pat.) Claims 7 and 17.

[6] Amarin Ex. 5 ('728 pat.) Claims 1, 13, and 16; Defs. Ex. 5 ('715 pat.) Claim 14; Defs. Ex. 6 ('677 pat.) Claims 1, 7, and 8; Defs. Ex. 7 ('652 pat.) Claims 1, 7, and 8; Defs. Ex. 8 ('560 pat.) Claims 4, 7, and 17.

[7] Defs. Ex. 5 ('715 pat.) Claim 14; Defs. Ex. 6 ('677 pat.) Claim 8; Defs. Ex. 7 ('652 pat.) Claim 8; Defs. Ex. 9 ('929 pat.) Claim 5.

[8] Defs. Ex. 1 (Toth Dep.) at 209:23-210:5.

[9] Defs. Ex. 3 (Toth Responsive Report) ¶¶ 373, 624.

[10] *Id.* ¶ 363.

[11] Defs. Ex. 4 (Toth Opening Report) ¶ 222.

[12] Defs. Ex. 1 (Toth Dep.) at 208:4-19, 211:6-15.

7. Dr. Toth opines that in order to believe 4 grams per day of purified EPA would achieve the claimed effects on LDL-C and Apo B, a POSA would need clinical data confirming that the results occurred in patients with triglycerides of at least 500 mg/dL.[13]

8. Amarin's patents disclose [redacted] let alone data from a convincing clinical study showing that 4 grams per day of purified EPA is effective in reducing triglycerides or achieves any of the claimed effects in any patient.[14]

9. The sole example in Amarin's patents discusses the possible design of a clinical trial that "will" take place at some future time "to determine the efficacy of [purified EPA] 2 g daily and 4 g daily, compared to placebo," in which "[t]he primary efficacy variable *will be* the percent change in fasting TG levels from baseline to Week 12," and variables such as changes in LDL-C and Apo B levels "will" be evaluated as secondary endpoints.[15] No results of this proposed clinical trial are disclosed in Amarin's patents.

10. Dr. Toth opines that 4 grams per day of purified EPA was first shown to achieve the claimed effects in Amarin's MARINE trial, which began in December 2009 and ended in October 2010,[16] and "demonstrated that 4 g per day of highly purified ethyl-EPA unexpectedly reduced TGs without increasing LDL-C when administered to patients with severely elevated TG levels" and "unexpectedly reduced apoB."[17]

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[13] Defs. Ex. 3 (Toth Responsive Report) ¶¶ 81 and 90.

[14] Defs. Ex. 1 (Toth Dep.) at 354:10-18.

[15] Amarin Ex. 5 ('728 pat.) at 13:24-16:50.

[16] Defs. Ex. 10 (Bays) at 683.

[17] Defs. Ex. 3 (Toth Responsive Report) ¶ 288; *see also, e.g.*, Defs. Ex. 2 (Toth Reply Report) [redacted]

11. Defendants' invalidity expert, Dr. Heinecke, opines that "if Dr. Toth were correct that a POSA would not have expected purified EPA to reduce triglycerides by at least 25%," "without increasing LDL-C levels," and while "reduc[ing] Apo B levels … , then a POSA would not have believed that the inventors of the asserted patents had achieved th[ose] result[s] based on the specification either."[18]

III. ARGUMENT

Amarin's motion for partial summary judgment should be denied. Nearly all of Amarin's arguments are moot because Defendants are not asserting invalidity based on anticipation, enablement, or indefiniteness. As to written description, there is at least a triable issue of fact as to whether the asserted claims are invalid. As explained below, the written description requirement is not met unless the patent specification "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351; *infra*, Part A. Here, Amarin's own expert contends that "as of the filing date" for Amarin's patents—March 2008[19]—a POSA would not have found it obvious to use a 4-gram dose of purified EPA, and would not have believed that purified EPA would achieve the clinical effects required by the asserted claims. *Infra*, Part B. Defendants disagree. But if the Court were to side with Amarin on this issue, Amarin fails to come to grips with the fact that its patents contain no evidence that 4 grams per day of purified EPA is effective or achieves any of the claimed effects either. *Infra*, Part C. Thus, if Amarin's expert testimony about the state of the art in March 2008 were accepted, the asserted claims would be invalid for lacking written

[18] Amarin Ex. 10 (Heinecke Reply Report) ¶¶ 183, 71, 204.

[19] As noted above, Amarin's patents claim priority to patent applications that were filed in February 10, 2009, and April 29, 2009. Amarin alleges that the claimed inventions were conceived earlier, in March 2008. The differences in these dates are not material to any issues in this brief. Dr. Toth has confirmed that his opinions "would not differ" if the state of the art and a POSA's expectations were assessed as of the actual filing dates of "February 10, 2009 or April 29, 2009" instead of the alleged invention date of March 2008. Defs. Ex. 4 (Toth Opening Report) ¶¶ 43-44. For the sake of simplicity, this brief refers to March 2008 as the relevant date.

description as a matter of law, and any additional expert testimony on the ultimate issue of invalidity is not required. *Infra*, Part D.

A. The written description requirement is not satisfied unless a POSA would believe based on evidence disclosed in the patent specification that the inventor possessed the claimed invention "as of the filing date."

Section 112 mandates that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it." 35 U.S.C. § 112. "[T]he hallmark of written description is disclosure," and "the test requires an objective inquiry into the four corners of the specification" to determine whether it "show[s] that the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351. Any "actual 'possession' or reduction to practice outside of the specification is not enough" to satisfy this requirement—"it is the specification itself that must demonstrate possession." *Id*. at 1352.

Section 112's disclosure requirement is not just a formality. It "plays a vital role in curtailing claims … that have not been invented, and thus cannot be described." *Id*. Section 112 thus "limits patent protection to those who actually perform the difficult work of 'invention'—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public." *Id.* at 1353. At bottom, "the purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'" *Id.* at 1353-54. "It is part of the *quid pro quo* of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time." *Id.* at 1354.

Merely disclosing the idea for an invention is not enough. "Patents are not awarded for academic theories, no matter how groundbreaking." *Id*. at 1353. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Id*. (quotation omitted). A specification that "hypothesizes" the invention "could be used" to achieve a claimed effect improperly "attempt[s] to preempt the future before it has arrived." *Id*.

at 1358 (quotation omitted). Merely repeating the claimed effect in the specification is also not enough—the Federal Circuit has "expressly rejected the argument that the written description requirement is necessarily met as a matter of law because the claim language appears in *ipsis verbis* in the specification." *Nuvo*, 923 F.3d at 1380 (quotation omitted). Moreover, "a description that merely renders the invention obvious does not satisfy the requirement." *Ariad*, 598 F.3d at 1352. "Thus, *a fortiori*, a description that does *not* render a claimed invention obvious does not sufficiently describe that invention." *Regents*, 119 F.3d at 1567.

The "level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad*, 598 F.3d at 1351. Thus, "the adequacy of the disclosure" is judged relative to "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue." *Id.* (quotation omitted). Where "[t]he state of the art at the time of filing was primitive and uncertain," a patentee is left "with an insufficient supply of prior art knowledge with which to fill … holes in its disclosure." *Id.* at 1358. The need for disclosure is often "particularly acute in the biological arts." *Id.* at 1353. An inventor cannot "merely recite a description of the problem to be solved" and then "leav[e] it to the pharmaceutical industry to complete an unfinished invention." *Id.* Such a "mere wish or plan for obtaining the claimed chemical invention" is inadequate. *Id.* at 1356. Where an inventor claims that "a claimed pharmaceutical compound actually achieves a certain result, . . . [Federal Circuit] case law provides that that result must be supported by adequate disclosure in the specification." *Nuvo*, 923 F.3d at 1384.

Importantly, "written description is determined as of the filing date" of the underlying patent application. *Ariad*, 598 F.3d at 1355. An inventor who has not yet achieved the claimed invention before filing his application, "by definition, could not have possession of, and disclose, the subject matter of [an invention] that did not even exist." *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004). "Thus, axiomatically," a patent with a filing date that

predates when the claimed invention was first achieved "cannot satisfy the written description requirement." *Id.*

B. Amarin's expert opines that, without clinical data, a POSA would not have found it obvious to use 4 grams per day of purified EPA, and would not have believed that purified EPA achieves the claimed effects.

Here, Amarin has asserted 15 patent claims that require treating a patient who has triglycerides of at least 500 mg/dL with 4 grams per day of purified EPA. Amarin's expert Dr. Toth opines that in order to find it obvious to use that dose of purified EPA, a POSA would need to see [redacted] Defs. Ex. 1 (Toth Dep.) at 211:6-15; *see also id.* at 211:24-212:16 (opining he would [redacted]). According to Dr. Toth, such a study would need to provide a [redacted] that 4 grams per day of EPA resulted in [redacted] *Id.* at 208:4-19. Although Dr. Toth concedes that prior art studies used 4 grams per day of purified EPA to reduce triglycerides, he opines that this dose still would not have been obvious. *Id.* at 207:3-18.

For example, Dr. Toth opines that a POSA would not have believed that administering 4 grams per day of purified EPA would result in the lipid effects required by 14 of the asserted claims—i.e., reducing triglycerides by at least 20-25%, avoiding an increase in LDL-C, and reducing Apo B. Despite a wealth of pre-2008 clinical data describing the effects of purified EPA on the claimed lipid parameters, Dr. Toth opines that there was a "lack of a reasonable expectation that one would get a reduction of at least about 25% in fasting triglycerides with purified EPA." Defs. Ex. 3 (Toth Responsive Report) ¶ 373. He opines that "it would not have been predictable, and there would have been no reasonable expectation of success, that a patient could avoid a substantial increase in LDL-C" upon administration with purified EPA. *Id.* ¶ 363. And Dr. Toth opines that "[a] person of ordinary skill in the art would have found VASCEPA's reduction in apo-B unexpected." Defs. Ex. 4 (Toth Opening Report) ¶ 222.

Dr. Toth holds these opinions despite the fact that clinical studies in the prior art showed that purified EPA reduced triglyceride levels by more than 25%, avoided any increase in LDL-C, and reduced Apo B. Amarin Ex. 6 (Heinecke Opening Report) ¶¶ 238-44. Despite these prior art studies, Dr. Toth maintains that a POSA would not have had a reasonable expectation of achieving the claimed effects with 4 grams per day of purified EPA because, for example, the studies "did not report the lipid effects of purified EPA in persons with triglyceride levels of at least 500 mg/dl." Defs. Ex. 3 (Toth Responsive Report) ¶ 90; *see also, e.g., id.* ¶ 81 (criticizing Defendants' prior art because it "did not study the effects of purified EPA or DHA in persons with triglyceride levels of at least 500 mg/dL"). Indeed, Dr. Toth criticizes nearly all of the prior art studies cited by Defendants because the studies, for example, "did not report LDL-C effects by baseline triglycerides," or did not "report that high purity EPA reduces apoB in persons with very high triglycerides." *Id.* ¶¶ 137, 147.

C. Amarin's patents disclose no data, and its experts opine that purified EPA was first shown to achieve the claimed effects *after* the filing date.

Defendants dispute Dr. Toth's opinions about the prior art, which Defendants contend would have rendered the asserted claims obvious to a POSA as of March 2008. *See* Amarin Ex. 6 (Heinecke Opening Report). If the Court were to accept Dr. Toth's testimony, however, it would be fatal to the asserted claims, which would be invalid for lack of written description.

Amarin's patent specification discloses no evidence that Amarin "actually invented" methods of using 4 grams per day of purified EPA that effectively reduce triglycerides, let alone methods that achieve the claimed effects of reducing triglycerides by 20-25%, avoiding LDL-C increases, or reducing Apo B. *Ariad*, 598 F.3d at 1351. As Dr. Toth admits, [redacted] Defs. Ex. 1 (Toth Dep.) at 354:10-18. At most, the specification alleges, without citing any evidence, that "upon treatment with a composition of the present invention, the Subject or Subject group exhibits one or more of the following outcomes"—followed by a laundry list of 25 categories of possible effects that

include, among many others, reductions in triglycerides, LDL-C, and Apo B levels. *E.g.*, Amarin Ex. 5 ('728 pat.) at 5:11-7:44.[20, 21]

"In light of the fact that the specification provides nothing more than the mere claim" that purified EPA would work to achieve the claimed effects, "the specification is fatally flawed." *Nuvo*, 923 F.3d at 1381. "It does not demonstrate that the inventor possessed more than a mere wish or hope that [purified EPA] would work, and thus it does not demonstrate that he actually invented what he claimed: an amount of [purified EPA] that is *effective* to" reduce triglycerides by 20-25% without increasing LDL-C and while reducing Apo B. *Id*. Thus, if the Court were to "f[i]nd upon [Amarin]'s insistence as part of its obviousness analysis that ordinarily skilled artisans would not have expected" the claimed results, the claims would lack written description support because "nothing in the specification would teach a person of ordinary skill in the art otherwise." *Id*. at 1377. Indeed, "[i]t is undisputed that there is no experimental data" in the patents, *id*. at 1373, which Dr. Toth contends a POSA would need just to find the claims obvious. *See, e.g.*, Defs. Ex. 3 (Toth Responsive Report) ¶ 90, Defs. Ex. 1 (Toth Dep.) at 211:6-15. And as a matter of law, "a description that does *not* render a claimed invention obvious does not sufficiently describe that invention." *Regents*, 119 F.3d at 1567.

Nor can Amarin rely on the patents' sole example, which discusses a hypothetical study that *could* be conducted to evaluate the claimed effects. Amarin Ex. 5 ('728 pat.) at 13:24-16:50. As the example makes clear, no such trial had taken place as of the filing date, and thus no results had been obtained. The example repeatedly states that "[t]he study *will* be a … Phase 3, multi-center study," a patient "screening visit (Visit 1) *will* occur," "[e]ligible patients *will* be randomly assigned … to receive orally [EPA] 2 g daily, [EPA] 4 g daily, or placebo," and "[t]he primary efficacy variable *will* be the percent change in fasting TG levels," among others. *Id.*

[20] Because all six patents-in-suit are related, their specifications are substantively identical, and thus Defendants cite only the '728 patent specification for simplicity.

[21] In fact, Amarin still has no clinical data to support many of the possible effects listed in the specification, e.g. "a reduction in total cholesterol of . . . at least about 75% (actual % change or median % change) compared to baseline." *Id.* at 7:39:44.

(emphasis added). Indeed, the entire description of the proposed study is in the future tense. *Id.* At best, the example "hypothesizes" that 4 grams per day of purified EPA may be effective for reducing triglycerides, and might later be shown to have the claimed effects, which improperly "attempt[s] to preempt the future before it has arrived." *Ariad*, 598 F.3d at 1353. It does not matter how "groundbreaking" the proposed study might be—only its "successful conclusion" could provide the necessary written description support. *Id.*

Indeed, in Dr. Toth's view, a POSA would have needed to see the results from that hypothetical study—which Amarin later conducted and named MARINE—in order to believe that 4 grams per day of purified EPA would achieve the claimed effects. Dr. Toth explains that MARINE assessed [redacted] and opines that this study demonstrated for the first time that [redacted] Defs. Ex. 2 (Toth Reply Report) ¶ 14. He points to MARINE as demonstrating "that 4 g per day of highly purified ethyl-EPA unexpectedly reduced TGs without increasing LDL-C when administered to patients with severely elevated TG levels," and that this "clinical trial also demonstrated that 4 g per day of highly purified ethyl-EPA unexpectedly reduced apoB." Defs. Ex. 3 (Toth Responsive Report) ¶ 288. In touting these purportedly "groundbreaking" results from MARINE, Dr. Toth emphasizes that it was not until [redacted] among other claimed effects. Defs. Ex. 2 (Toth Reply Report) ¶ 183 (emphasis in original).

Amarin likewise argues that MARINE's "successful conclusion" (*Ariad*, 598 F.3d at 1353) did not occur until *after* the patents' filing date—when the MARINE trial was completed in October 2010. Defs. Ex. 10 (Bays) at 683. As Amarin admits, the asserted claims are directed to "achiev[ing] (or avoid[ing]) certain lipid effects in accordance with the important results from the MARINE trial." Br. 4. Indeed, Amarin insists that it was not until it "spent years conducting [such] clinical trials" that it "showed that Vascepa safely lowers TG levels in patients with

severe hypertriglyceridemia without increasing LDL-C," among the other claimed "improvement[s] upon prior therapies." Br. 2. Echoing Dr. Toth's opinions, Amarin alleges that these "clinical trial results disproved the conventional wisdom" at the time. *Id.*

Dr. Toth's opinions and Amarin's arguments are fatal to the asserted claims. Because "the important results from the MARINE trial" (*id*. at 4) did not exist, at the earliest, until October 2010, they cannot show that "the inventor had possession of the claimed subject matter as of the filing date"—i.e., in March 2008, or at the latest, in April 2009. *Ariad*, 598 F.3d at 1351. In other words, if Amarin were correct that the claimed effects of purified EPA were not discovered until the MARINE trial, then "by definition, [Amarin] could not have possession of, and disclose, the subject matter of [an invention] that did not even exist" when it filed its patents. *Chiron*, 363 F.3d at 1255. Section 112 "plays a vital role in curtailing [such] claims … that have not been invented, and thus cannot be described." *Ariad*, 598 F.3d at 1352.

Amarin cannot avoid that result by contending that it possessed some internal, non-public knowledge about the claimed effects as of the patents' filing date. Even if Amarin had proof of those effects at the time (and there is no evidence that it did), any such "actual 'possession' or reduction to practice outside of the specification is not enough." *Id*. Again, "it is the specification itself that must demonstrate possession"—here, it does not. *Id.*

Amarin's insistence that "the technology at issue is complex" supports that conclusion. Br. 5; *see also id*. at 9-10. Any alleged "complexity" of the claimed invention would only raise the "level of detail required to satisfy the written description requirement"—and highlight the lack of disclosure in Amarin's patents. *Ariad*, 598 F.3d at 1351. Amarin's view that complexity or "skeptic[ism] of the results claimed is evidence of *validity*" is mistaken. Br. 14. Amarin cites a case about obviousness (*WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1335 (Fed. Cir. 2016)), but ignores that for written description, skepticism has the opposite effect and is evidence of *in*validity: If "[t]he state of the art at the time of filing w[ere] … uncertain," that would only reinforce the conclusion that there was "an insufficient supply of prior art knowledge with which to fill the gaping holes in [Amarin's] disclosure." *Ariad*, 598 F.3d at 1358.

As the proponent of these arguments and Dr. Toth's opinions, Amarin "cannot reasonably dispute" them. *Nuvo*, 923 F.3d 1380. Indeed, if the Court were to "rel[y] on, or 'accept[]' [Amarin]'s previous inconsistent position" that the prior art did not teach the claimed effects of purified EPA for purposes of obviousness, Amarin would be "judicially estopped" from asserting otherwise for purposes of written description—warranting judgment of invalidity as a matter of law. *Hamilton v. State Farm Fire & Cas. Co.*, 270 F.3d 778, 782 (9th Cir. 2001) ("Judicial estoppel is an equitable doctrine that precludes a party from gaining an advantage by asserting one position, and then later seeking an advantage by taking a clearly inconsistent position."); *Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1302 (Fed. Cir. 2002) (applying "regional circuit law" in finding that "judicial estoppel applies").

D. There is no requirement for expert testimony on the ultimate issue of written description support, which can be resolved as a matter of law based on testimony by Amarin's own experts.

Amarin's motion ignores the relevant legal standards and evidence, and fails to grapple with the consequences of its litigation positions. Instead, its motion purports to turn on a single premise—that "expert testimony is *required* to support an invalidity defense." Br. 9. Even if that premise were true, however, expert testimony *does* support Defendants' written description defense: Amarin's *own* expert testimony.

The testimony of Defendants' expert, Dr. Heinecke, further supports that defense. As he explained for each of the claimed results, "if Dr. Toth were correct that a POSA would not have expected purified EPA to reduce triglycerides by at least 25%," "without increasing LDL-C levels," and while "reduc[ing] Apo B levels … , then a POSA would not have believed that the inventors of the asserted patents had achieved th[ose] result[s] based on the specification either." Amarin Ex. 10 (Heinecke Reply Report) ¶¶ 183, 71, 204. Amarin's attempt to frame this testimony as a "new argument" offered on reply lacks merit. Br. 13. Again, Defendants' affirmative argument, and Dr. Heinecke's opinion, is that the asserted claims are obvious. It is only if Amarin and Dr. Toth's view of the facts were accepted that Defendants would contend

the claims lack written description. Dr. Heinecke's reply testimony properly "contradict[s] or rebut[s] evidence on the same subject matter identified by another party," namely Amarin, because it directly addresses the opinions expressed by Dr. Toth. Fed. R. Civ. P. 26(a)(2)(D)(ii).[22]

To the extent Amarin contends that Defendants need an expert to opine on the ultimate issue of validity, Amarin is incorrect. As a general rule, while expert testimony "is not objectionable just because it embraces an ultimate issue," Fed. R. Evid. 704(a), ultimate issue testimony is also not required. That is especially true for the ultimate issue of written description, which is "an objective inquiry into the four corners of the specification." *Ariad*, 598 F.3d at 1351. "After all, it is in the patent specification where the written description requirement must be met," not in extrinsic evidence like expert testimony. *Rochester*, 358 F.3d at 927. While such evidence may be considered, "[a] patent also can be held invalid for failure to meet the written description requirement based solely on the face of the patent specification." *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1347 (Fed. Cir. 2011).

The Federal Circuit has thus rejected the "argu[ment] that [a patent challenger] failed to present any expert testimony" on written description, holding that "there is no strict requirement for extrinsic evidence (expert or otherwise) … [to] determine whether the written description requirement has been satisfied." *Adang*, 2007 WL 3120323, at *2. In fact, the Federal Circuit has repeatedly found patents invalid for lacking written description as a matter of law, without relying on expert testimony. *See, e.g.*, *Centocor*, 636 F.3d at 1347 (reversing denial of JMOL and invalidating claims for lack of written description); *PIN/NIP, Inc. v. Platte Chem. Co.*, 304

[22] The lack of disclosure in Amarin's patents is also relevant to Dr. Heinecke's affirmative opinions on obviousness, which Amarin does not dispute are within the proper scope of reply. *See, e.g.*, *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1374 (Fed. Cir. 2005) (finding obviousness where the asserted patent "sets forth no human clinical or laboratory data showing the safety and tolerability of the treatment methods claims," and thus "adds nothing beyond the teachings of the [prior art]"); *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012) (finding obviousness and rejecting patentee's "argu[ment] that [the prior art] would not give a skilled artisan an expectation of success" for drug safety, because "neither does the [asserted] patent," which was "not based on testing in humans").

F.3d 1235, 1248 (Fed. Cir. 2002) (same); *Rochester*, 358 F.3d at 927 (same). Thus, the fact that Dr. Heinecke "did not provide an ultimate opinion that [the asserted] patents … are invalid based on a theory of lack of written description" does not preclude Defendants from pursuing that defense at trial. *Tap Pharm. Prod., Inc. v. Owl Pharm., L.L.C.*, 2002 WL 34381130, at *2 (N.D. Ohio Sept. 16, 2002) (denying patentee's motion *in limine* to preclude defendants from presenting written description defense).

In arguing otherwise, Amarin cites only four cases on written description.[23] Br. 10 n.12, 12 n.14. None involved a case like this one, where the patentee itself takes the position that a POSA would not have believed the claimed invention would work. Nor do any of Amarin's cases set forth a rule that expert testimony is categorically required. On the contrary, *Lucent Technologies Inc. v. Gateway, Inc.* recognizes that "expert testimony is not always required to prove invalidity" for "lack of written description." 2007 WL 1449804, at *2 (S.D. Cal. May 15, 2007). For that principle, the *Lucent* court cited the Federal Circuit's decision in *Rochester*, which held that "the patent itself may evidence invalidity." *Id*. (citing 358 F.3d at 927). The *Lucent* court found that testimony was needed only after specifically distinguishing *Rochester*, where the patentee "acknowledged that there was no availing knowledge in the prior art" regarding the claimed invention. *Id*. at *3. In *Lucent*, "such assertions ha[d] not been made." *Id*. By contrast, here (as in *Rochester*), Amarin *has* "acknowledged that there was no availing

[23] Amarin's other cases purporting to require expert testimony involved other issues, such as obviousness, which do not turn on the face of the patent itself but on extrinsic evidence. *See Allergan, Inc. v. Barr Labs., Inc.*, 501 F. App'x 965, 972 (Fed. Cir. 2013) (obviousness); *Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1309-10 (Fed. Cir. 2011) (prior invention); *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc.*, 249 F.3d 1341, 1353-54 (Fed. Cir. 2001) (anticipation, obviousness); *Centricut, LLC v. Esab Grp., Inc.*, 390 F.3d 1361, 1369-70 (Fed. Cir. 2004) (infringement); *Diodem, LLC v. Lumenis Inc.*, 2005 WL 6220667, at *7 (C.D. Cal. Jan. 10, 2005) (utility, enablement); *INVISTA N. Am. S.A.R.L. v. M&G USA Corp.*, 951 F. Supp. 2d 626, 651-52 (D. Del. 2013) (obviousness); *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1267 (Fed. Cir. 2008) (anticipation, obviousness); *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1316 (Fed. Cir. 2002) (anticipation); *Vectura Ltd. v. GlaxoSmithKline LLC*, 2019 WL 1244942, at *2-4 (D. Del. 2019) (anticipation).

knowledge in the prior art" regarding the claimed invention. *Id*. Indeed, as discussed above, that is the premise of Dr. Toth's opinion that the asserted claims are nonobvious.

McKesson Automation, Inc. v. Swisslog Holding AG, 2009 WL 3648455 (D. Del. Oct. 30, 2009), is also inapposite. While framed in part as a written description challenge, the issue there was "indefiniteness"—whether "one of ordinary skill in the art would be unable to understand" certain claim terms that were not expressly defined in the specification. *Id*. at *27-28. The patent challenger submitted no evidence that "one of ordinary skill in the art could not understand the term[s]," whereas the patentee's expert "explained in detail how one of ordinary skill would understand" them. *Id*. at *28. Thus, the evidence was one-sided in favor of the patentee and warranted summary judgment. By contrast, the issue here is not whether a POSA would *understand* claims about the effects of purified EPA, but whether a POSA would *believe* those effects. On that issue, Amarin's own expert testimony is that a POSA would not have that belief, which for written description purposes is evidence of invalidity.

Similarly, in Amarin's other two cases, the only record evidence was that the claims were adequately described. In *AAT Bioquest, Inc. v. Texas Fluorescence Labs., Inc.*, the challenger's "written description arguments [we]re hopelessly flawed for multiple reasons" on the merits, and its "briefs rel[ied] mostly on attorney argument, as they include[d] virtually no citations to legal authority, and only minimal citations to mostly undifferentiated masses of evidence." 2015 WL 1738402, at *7, *5 (N.D. Cal. Apr. 13, 2015). "In contrast, [the patentee]'s request for a judgment of 'no invalidity' on the basis of written description include[d] competent expert testimony" that "point[ed] to specific support in the relevant patent applications." *Id*. at *5. Likewise, in *General Electric Co. v. SonoSite, Inc.*, the challenger did no "more than state the legal standard and then declare that it has been satisfied," whereas the patentee "cite[d] a passage from the specification that describe[d] how [the claimed effect] occurs in the invention," which the challenger "ma[de] no effort to address." 641 F. Supp. 2d 793, 818-19 (W.D. Wis. 2009). None of that is true here. Defendants rely on specific opinions by Amarin's own expert that the claimed effects of purified EPA were unexpected—opinions that Amarin "cannot reasonably

dispute," *Nuvo*, 923 F.3d 1380—and Amarin points to "nothing in the specification [that] would teach a person of ordinary skill in the art otherwise." *Id*. at 1377.

IV. CONCLUSION

Because there is at least a triable issue of fact as to whether the asserted claims are invalid for lack of written description, partial summary judgment should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to FRCP 5(b), I certify that I am an employee of BROWNSTEIN HYATT FARBER SCHRECK, LLP, and on this 30th day of August, 2019, I served the document entitled **DEFENDANTS' OPPOSITION TO AMARIN'S MOTION FOR PARTIAL SUMMARY JUDGMENT**, on the parties listed below via the following:

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